In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS No. 19-1998V UNPUBLISHED

TRACY RENEE RUDDY,

Petitioner,

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SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: March 5, 2021

Special Processing Unit (SPU); Findings of Fact; Site of Vaccination Influenza (Flu) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA)

Jeffrey S. Pop, Jeffrey S. Pop & Associates, Beverly Hills, CA, for Petitioner.

Lynn Christina Schlie, U.S. Department of Justice, Washington, DC, for Respondent.

FACT RULING¹

On December 30, 2019, Tracy Renee Ruddy filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10, *et seq.*² (the "Vaccine Act"). Petitioner alleges that she suffered a right shoulder injury related to vaccine administration ("SIRVA") as a result of an influenza ("flu") vaccine administered on December 15, 2017. Petition at 1. The case was assigned to the Special Processing Unit ("SPU") of the Office of Special Masters.

¹ Because this unpublished fact ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the fact ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

For the reasons discussed below, I find that the vaccination in question was more likely than not administered in Petitioner's right shoulder.

I. Relevant Procedural History

Ms. Ruddy filed the petition on December 30, 2019 (ECF No. 1). On January 9, 2020, she filed a declaration and medical records as Exhibits 1-16, along with a statement of completion (ECF Nos. 6-8). The case went through the pre-assignment review process and was thereafter assigned to the SPU on January 16, 2020 (ECF No. 10).

The initial status conference was held on April 14, 2020 (ECF No. 12). On June 15, 2020, Respondent filed a status report providing counsel's informal assessment of the claim. Respondent's Status Report, filed June 15, 2020 (ECF No. 13). In it, Respondent requested that additional medical records be filed, but also noted that the vaccine administration record indicated that the vaccine had been administered in Petitioner's *left* arm – contrary to her Petition's allegations. *Id.* at *2 (*citing* Exs. 2 at 1 and 3 at 123, 146).

On June 29, 2020, I directed Petitioner to file the requested medical records and a statement of completion by August 12, 2020 (ECF No. 14). Thereafter, I indicated that a telephonic status conference would be held to discuss how the parties wished to resolve the factual question concerning the site of vaccine administration. *Id*.

On August 11, 2020, Petitioner filed medical records as Exhibits 17 and 18 (ECF No. 15). On August 12, 2020, Petitioner filed a status report addressing Respondent's records requests (ECF No. 16). Petitioner stated that all updated medical records had been filed and that she believed there was "overwhelming evidence" that she complained about right arm/shoulder pain after vaccination to many health care providers, demonstrating that the vaccine administration record was erroneous. *Id*.

On October 20, 2020, a telephonic status conference was held (ECF No. 18). During the conference, Petitioner's counsel requested the opportunity to obtain additional evidence concerning the site of vaccination. *Id.* The parties did not object to a ruling on the written record concerning the site of vaccine administration after Petitioner had the opportunity to file additional evidence. *Id.* On December 9, 2020, Petitioner filed additional witness declarations as Exhibits 19-23 and a statement of completion (ECF Nos. 19-20). The situs issue is now ripe for determination.

II. Issue

At issue is whether Petitioner received the vaccination alleged as causal in her right arm. 42 C.F.R. § 100.3(a) XIV.B. (2017) (influenza vaccination).

III. Authority

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Section 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. In *Lowrie*, the special master wrote that "written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Lowrie*, 2005 WL 6117475, at *19.

The United States Court of Federal Claims has recognized that "medical records may be incomplete or inaccurate." *Camery v. Sec'y of Health & Hum. Servs.*, 42 Fed. Cl. 381, 391 (1998). The Court later outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery*, 42 Fed. Cl. at 391 (citing *Blutstein v. Sec'y of Health & Hum. Servs.*, No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering

such testimony must also be determined. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A special master may find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." Section 13(b)(2). "Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table." *Id*.

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing § 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

IV. Finding of Fact

Based upon a review of the entire record, including all medical records, declarations, and additional evidence filed, I find that Petitioner's December 15, 2017 flu vaccine was, more likely than not, administered in her right arm. I base my finding on the following evidence:

- Exhibit 2 at 1, a vaccine administration record indicating that a flu vaccine was administered to Petitioner on December 15, 2017. The site of vaccination is recorded as "Left Deltoid." *Id.*
- Exhibit 4 at 6, a record of a January 3, 2018 visit to Sierra Doctors Medical Group. The record noted that Petitioner was seen for arm pain, explaining that she was "[h]ere with right upper arm pain three weeks after flu shot which she noted was given more proximally than usual." *Id*.
- Exhibit 3 at 138-39, a record of a January 16, 2018 telephone encounter with the Veterans Administration Sierra Nevada Health Care System ("VA Sierra"). The record indicated that Petitioner reported that she "had flu shot and hit her nerve, NON-VA Dr. gave her steroids, and she was fine until

- steroid wore off and now she's having problem. She is having extreme right arm pain, can't sleep X 3 days." *Id*.
- Exhibit 3 at 137-38, a record of an April 9, 2018 telephone encounter with VA Sierra noting that Petitioner reported "she is still having pain in her Right upper arm, deltoid area where she got her flu shot." *Id.* at 137.
- Exhibit 3 at 136, a record of an April 17, 2018 telephone encounter with VA Sierra stating that Petitioner requested a return call from a nurse "to discuss consult to orthopedics for right shoulder pain."
- Exhibit 3 at 58, an April 19, 2018 record referring Petitioner for an orthopedic evaluation due to "RIGHT shoulder pain since December 2017."
- Exhibit 6 at 6, a record of a May 14, 2018 orthopedic consultation with Dr. Sukhdeep Sagoo for right shoulder pain. The record indicated that Petitioner complained that she "[h]ad a flu shot in December and shoulder [has] been hurting ever since then." Id. The record further stated that Petitioner reported "right shoulder pain since December of 2017. Patient reports that she had a flu shot in the right shoulder very high up which she thinks may have led to the pain starting. She reports that when she got the injection . . . it hurt persistently for 4-5 days." Id.
- Exhibit 3 at 123, a record of a June 6, 2018 appointment with Dr. James Irons for "right shoulder pain." The record explained that Petitioner "was seen by woman's clinic in Auburn on December 15; at the end of her GYN exam, she received a flu shot in her right shoulder. Tracey is a paramedic and medical assistant; she states shot was given at top of shoulder 'in wrong place' near location of biceps tendon (long head)." Id. Petitioner then developed pain and limited range of motion. Id. The record added that "the injection site was documented at left shoulder, though she insists injection was her RIGHT shoulder." Id.
- Exhibit 3 at 27, a record of Petitioner's July 8, 2018 right shoulder MRI noting her history as "[r]ight shoulder severe pain since FLU shot in December 15, 2017."
- Exhibit 7 at 36-37, the operative report for Petitioner's August 23, 2018 right shoulder surgery. The report noted that the surgery was indicated because Petitioner reported "that she had a flu shot in the right shoulder very high up

according to her, which is about the time she started noticing some right shoulder pain as well as some weakness." *Id.*; see also id. at 33 (August 23, 2018 pre-operative examination noting that Petitioner "has had right shoulder pain since December 2017. The patient reports that she had a flu shot in the right shoulder very high up, which is about the time when the pain started").

- Exhibit 7 at 47, a record of Petitioner's September 12, 2018 post-operative physical therapy initial evaluation, noting that Petitioner reported "an onset of right shoulder pain in December 2017 after she had a flu shot" and that she lost mobility thereafter.
- Exhibit 1, Petitioner's declaration, stating that a licensed vocational nurse administered the December 15, 2017 flu vaccine in her right arm. *Id.* at ¶ 6. Petitioner acknowledged that the VA medical records indicated that the injection site was her left arm. *Id.* at ¶ 7. She explained, "[w]hen I spoke with the Risk Manager in Reno, he did a mock immunization on the computer and the system automatically defaults the site of vaccine injection to the left." *Id.* Petitioner averred that within two days of vaccination, she developed right shoulder pain and limited range of motion. *Id.* at ¶ 8.
- Exhibit 19, a declaration from Shannon Hatton, Petitioner's walking partner, averring that approximately 2-3 years ago Petitioner "was angry because they gave her a vaccination. She pointed to her right shoulder and said it was too high up and that her shoulder really hurt." *Id.* at ¶ 6. Ms. Hatton explained, "I am sure it was her right arm that was injured because when we walk together we always walk on the same side and she walks to my left. I remember that she pointed to her right arm which would be closest to my body and she pointed where on her right shoulder she believed the shot was too high." *Id.* at ¶ 7.
- Exhibit 20, a declaration from Frances Marie Loop. Ms. Loop averred that she is a good friend of Petitioner and works as a caregiver for elderly people and people recovering from injuries or surgeries. *Id.* at ¶¶ 3, 5. Ms. Loop stated that a day or two after the flu shot, Petitioner expressed concern about the pain in her shoulder where the vaccine was injected. *Id.* at ¶ 6. Ms. Loop averred, "I was curious why she chose her dominant arm for the shot. Tracy said that since being a paramedic she would always administer to patient's left and herself always right. I got it because I remember thinking the same when I worked at a nursing facility." *Id.*

- Exhibit 21, a declaration from Petitioner's spouse, Edward Hustad, explaining that sometime before Christmas in 2017, Petitioner came home and said she had gotten a flu shot and was in pain because it was given too high in her arm. *Id.* at ¶ 5. Mr. Hustad stated that Petitioner pointed to the injection site and it was toward the top of her right shoulder. *Id.* He added that thereafter, Petitioner had difficulty doing everyday tasks because it was difficult to use her right arm. *Id.* at ¶ 6.
- Exhibit 22, a declaration from Petitioner's adult child Lisa Ginestet-araki. Ms. Ginestet-araki reported that she speaks to her mother almost every day after work and remembered the day Petitioner received the vaccination. *Id.* at ¶ 5. She added that she spoke to her mother the day of vaccination and the following day, and that on the day after the vaccination, her mother "was upset by how much her shoulder hurt. She was in pain and she had trouble using her right arm." *Id.* at ¶¶ 5-6. Ms. Ginestet-araki further explained that when she visited Petitioner at Christmas in 2017, Petitioner complained that "she could not lift a blow dryer because her right arm hurt so bad from the flu shot she received earlier in the month." *Id.* at ¶ 7.
- Exhibit 23, a declaration from Petitioner's adult child Laura Ruddy. Ms. Ruddy averred that she speaks to her mother almost every day. Id. at ¶ 5. Ms. Ruddy averred that Petitioner called her around mid-December 2017 and "complained about just receiving a flu shot in her right arm and experiencing pain in her right shoulder." Id. at ¶ 6. Ms. Ruddy added that just after Christmas in 2017 she visited Petitioner and "noticed that my mother could hardly use her right arm at all. My mom had difficulty drying her hair, lifting something into the oven, and washing dishes. Since it was her dominant right arm I could see that it was really debilitating. She had almost no range of motion in her right arm." Id. at ¶ 8.

As the above medical entries reveal, with the exception of the vaccine administration record itself Petitioner's subsequent medical records *consistently* document that she reported that the flu vaccine was administered in her right shoulder. She also consistently reported right shoulder pain related to the flu vaccine. And Petitioner was seen for medical treatment 19 days post-vaccination, reporting at that time right shoulder pain from the flu vaccine. She continued thereafter to report right shoulder pain

associated with the vaccination. Numerous fact declarations make the same assertion.³ Given the above, a preponderance of the evidence supports a finding that it is more likely than not that the vaccine was administered in Petitioner's right arm.

V. Scheduling Order

The situs issue is the sole matter identified by Respondent as requiring additional development – and its resolution in Petitioner's favor suggests the matter might be amenable to settlement. To that end, Petitioner shall proceed with preparing a demand, with supporting documentation, for Respondent's consideration. I understand that Respondent cannot provide a response to this demand until he has obtained formally his client's position. However, the parties should strive to be in a position to immediately discuss damages once Respondent indicates he is amenable to consideration of Petitioner's demand after Respondent's review is complete. In addition, it is sensible for Petitioner to calculate her likely damages as quickly as possible in any case pending in SPU.

Accordingly:

- Petitioner shall file, by no later than <u>Wednesday, April 07, 2021</u>, a status report providing the following information:
 - Whether and when Petitioner provided a demand for damages with supporting documentation to Respondent's counsel;
 - Whether there is a Medicaid lien in this case and, if so, when Petitioner anticipates providing documentation of the lien to Respondent;
 - Petitioner's current treatment status and condition;
 - o Whether all updated medical records have been filed; and
 - A list of each component of damages allegedly suffered by Petitioner.
- Respondent shall file a status report indicating how he intends to proceed in this case by <u>Friday</u>, <u>May 07</u>, <u>2021</u>. At a minimum, the status report shall indicate whether he is willing to engage in tentative discussions regarding settlement or

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³ Petitioner's assertion in her declaration that the VA system automatically defaults to a vaccination site of left deltoid is of interest, although it does not weigh heavily in my finding because the evidence supporting it is not strong.

proffer, is opposed to negotiating at this time, or that the Secretary has not yet determined his position. In the event Respondent wishes to file a Rule 4(c) report, he may propose a date for filing it, but shall indicate his position on entering into negotiations regardless of whether he wishes to file a Rule 4(c) Report.

Any questions about this order or about this case may be directed to OSM staff attorney Eileen Vachher at (202) 357-6388 or Eileen_Vachher@cfc.uscourts.gov. IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master